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EUROPEAN PATENT APPLICATION (12) (43) Date of publication: (51) Int Cl.: A61K 47/10^(2017.01) A61K 47/26 (2006.01) 29.04.2020 Bulletin 2020/18 A61K 47/32^(2006.01) A61K 47/36 (2006.01) A61K 9/10 ^(2006.01) A61K 47/38 (2006.01) (21) Application number: 19209609.7 A61K 9/16 (2006.01) A61K 31/4178 (2006.01) (22) Date of filing: 06.10.2017 (84) Designated Contracting States: (72) Inventors: AL AT BE BG CH CY CZ DE DK EE ES FI FR GB Paduszynski, Piotr GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO 98-346 Skomlin (PL) PL PT RO RS SE SI SK SM TR Czescik, Katarzyna **Designated Extension States:** 54-104 Wroclaw (PL) BA ME · Potaczek, Piotr 54-129 Wroclaw (PL) **Designated Validation States:** MA MD Han-Marek, Malgorzata 02-999 Warszawa (PL) (30) Priority: 10.10.2016 PL 41904716 Han, Tomasz 08.05.2017 PL 42150517 55-095 Szczodrze (PL) Han, Stanislaw (62) Document number(s) of the earlier application(s) in 51-423 Wroclaw (PL) accordance with Art. 76 EPC: 17797439.1 / 3 522 929 (74) Representative: Krekora, Magdalena ul. Gorna 95 (71) Applicants: PL-32-091 Michalowice (PL) Przedsiebiorstwo Produkcji Farmaceutycznej Hasco-Lek S.A. Remarks: 51-131 Wroclaw (PL) This application was filed on 16-11-2019 as a divisional application to the application mentioned Centrum Badawczo-Rozwojowe Novasome sp. z 0.0. under INID code 62. 51-423 Wroclaw (PL)

(54) A COMPOSITION COMPRISING FURAZIDIN AND A METHOD OF ITS MANUFACTURING

(57) A pharmaceutical oral composition comprising furazidin in the form of powder or/and granules or/and coated granules, which comprises from 0.5% by weight to 95% by weight of furazidin and at least one bulking agent in an amount from 5% by weight to 99% by weight

chosen from the group consisting of starch, gelatinized starch, microcrystalline cellulose, lactose, glucose, mannitol, sorbitol, anhydrous colloidal silica, talc, dextrins or/and their mixture.

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Description

TECHNICAL FIELD

⁵ **[0001]** The object of the present invention is a pharmaceutical oral composition comprising furazidin, and a method of manufacturing it.

BACKGROUND ART

- 10 [0002] Furazidin (Furaginum) is a derivative of nitrofuran, broad-spectrum chemotherapeutic agent. It acts against both Gram-positive and Gram-negative bacteria. It demonstrates bacteriostatic effect inter alia on Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus faecalis, Salmonella, Shigella, Proteus, Klebsiella, Escherichia, Enterobacter. Furazidin is used for treatment and prophylaxis of acute and chronic urinary tract infections.
- [0003] Furazidin is administered in oral form in the form of tablets. Tablets comprise corn starch, sucrose, colloidal silicon dioxide and stearic acid as excipients. The dosage form of a tablet is not very suitable for some groups of patients who have problems with swallowing e.g. children or elderly persons.

[0004] It has been found unexpectedly, that it is possible to deliver to those groups of patients a new oral dosage form which will be more suitable for them.

20 DISCLOSURE OF THE INVENTION

[0005] Oral pharmaceutical composition comprising furazidin according to the invention is in the form of powder or/and granules or/and coated granules, and it comprises from 0.5% by weight to 95% by weight of furazidin and it comprises at least one bulking agent in an amount from 5% by weight to 99% by weight chosen from the group consisting of starch,

²⁵ gelatinized starch, microcrystalline cellulose, lactose, glucose, mannitol, sorbitol, talc, anhydrous colloidal silica, dextrins or/and their mixture.

[0006] The composition according to the invention may be directly administered to a patient. It may be used for preparation of oral suspension or/and a filling of hard capsule. It may be used for preparation of pellets or/and coated pellets or/and minitablets or/and coated minitablets, and they may constitute a filling of hard capsules. The composition

- ³⁰ according to the invention may be suspended in a dispersion phase what enables filling of soft capsule or/and hard capsule.
 - **[0007]** The composition has non-modified release characteristics.
 - **[0008]** The composition has modified release characteristics. The term "modified release" shall be understood as prolonged release, delayed release, pulsatile release or accelerated release.
 - ³⁵ **[0009]** The composition comprises at least one compound having binding or/and coating properties in an amount from 0.1% by weight to 30 % by weight chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polymers of vinyl alcohol derivatives, chemically modified cellulose derivatives, polyvinylpyrrolidones and/or polyethylene oxides. Saccharides used in the composition are e.g. sucrose or/and dextrins, polyhydric alcohols are e.g. sorbitol, mannitol, and chemically modified cellulose derivatives
- 40 are e.g. hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose phthalates or/and cellulose acetate. Polyvinylpyrrolidones used in the compositions are e.g. povidone K15/17 or/and povidone K25, whereas polyethylene oxides are e.g. PEG 400 or/and PEG 6000.

[0010] The composition comprises at least one compound having emulsifying properties in an amount from 0.1% by weight to 45% by weight chosen from the group consisting of phospholipids, polyoxyethylene sorbitan derivatives, fatty

⁴⁵ acids and/or fatty alcohols. Phospholipids used in the compositions are soya lecithin or/and sunflower lecithin, and sorbitan derivatives are e.g. sorbitan sesquioleate. Fatty acids used in the composition are e.g. oleic acid, fatty alcohols are e.g. oleic alcohol.

[0011] The composition comprises at least one compound chosen from the group of surfactants (e.g. sodium lauryl sulfate) in an amount from 0.1% by weight to 15% by weight.

- 50 [0012] The composition comprises at least one lubricant in an amount from 0.1% by weight to 10% by weight. Lubricants used are e.g. stearic acid, magnesium stearate, talc or/and their mixture.
 [0013] The composition comprises at least one substance chosen from the group consisting of sweetening agents, flavoring agents and buffering agents in an amount from 0.01% by weight to 25% by weight. The composition may
- comprise just one of these agents or any of their mixtures. Sweetening agents used are e.g. sucrose, acesulfame K,
 sodium saccharin or/and sucralose. Flavoring agents comprised in the composition are e.g. orange, cherry, lemon or/and
 banana flavor, and buffering agents are e.g. sodium dihydrogen phosphate, sodium hydrogen phosphate, citric acid
 or/and sodium citrate.

[0014] The object of the present invention is also a method of manufacturing oral composition comprising furazidin

and bulking agent as defined above which consists in that a water or/and organic solution of the substance having binding properties chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polymers of vinyl alcohol derivatives, chemically modified cellulose derivatives, polyvinylpyrrolidones and/or polyethylene oxides having concentration of 0.1% by weight to 30 % by weight

⁵ is prepared, then furazidin in an amount from 0.5% by weight to 95 % by weight is mixed with the substance having emulsifying properties and/or with the bulking agent, then the mixture of furazidin with the substance having emulsifying properties and/or with the bulking agent is granulated with addition of the binding substance solution, after granulation the obtained granules are calibrated and dried, and then they are mixed with bulking agent and/or a lubricant and/or a surfactant and/or a sweetening agent and/or a flavoring agent and/or a buffering agent. The composition obtained by this method is in the form of granules.

[0015] Granules directly after drying or after drying and calibration, and before mixing with other substances is coated with coating agents.

[0016] The object of the present invention is also a method of manufacturing the composition comprising furazidin and bulking agent as defined above in the form of a powder. The method consists in that furazidin in an amount from

- 0.5 to 95% by weight is mixed with a bulking agent chosen from the group consisting of starch, gelatinized starch, microcrystalline cellulose, lactose, glucose, mannitol, sorbitol, talc, anhydrous colloidal silica, dextrins or/and their mixture or/and additionally with a binding agent chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polymers of vinyl alcohol derivatives, chemically modified cellulose derivatives, polyvinylpyrrolidones and/or polyethylene oxides or/and an emulsifying agent chosen
- from the group consisting of phospholipids, polyoxyethylene sorbitan derivatives, fatty acids and/or fatty alcohols or/and a surfactant or/and a lubricant or/and a sweetening agent or/and a flavoring agent or/and a buffering agent.
 [0017] The examples below illustrate the invention.

Example 1

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- [0018] Quantitative-qualitative composition of the formulation is depicted below.
 - No. Name of the ingredient % wt/wt 1. Furazidin 50 2. Gelatinized corn starch 30.5 3. Sucrose 16.9 4. Anhydrous colloidal silica 0.5 5 Stearic acid 50 2.1 SUM: 100
- **[0019]** Description of technological process: in the apparatus for wet granulation e.g. in a mixer granulator the ingredients 1 and 2 were placed. A solution of binding agent being a water solution of the ingredient 3 was prepared. The ingredients 1 and 2 were mixed until smooth, however not shorter than 5 minutes. Granulation was performed with use of the water solution of the ingredient 3. The water solution of the ingredient 3 shall have the concentration from 50 to 100 % wt/wt, and it is possible to use maximal ratio of the solvent : ingredient 3 as 1:2. After granulation the granules obtained were calibrated and dried to achieve dryness from 0.5 to 15%. In case of need the dried granules were calibrated. The ingredient 4 was added. The whole was mixed until smooth, but not less than 3 min. The ingredient 5 was added. The whole was mixed until smooth, but not less than 3 min. The ingredient 6 was a filling for hard capsules or may be used for obtaining pellets or minitablets, where may then constitute a filling for hard capsules.

50 Example 2

[0020] Quantitative-qualitative composition of the formulation is depicted below.

No.	No. Name of the ingredient	
1.	Furazidin	1,111
2.	Gelatinized corn starch	0,678

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No.	Name of the ingredient	% wt/wt
3.	Sucrose	0,376
4.	Anhydrous colloidal silica	0,011
5.	Stearic acid 50	0,047
6.	Orange flavor	2,502
7.	Acesulfame potassium	0,084
8.	Sodium saccharin	0,084
9.	Sucralose	0,133
10.	Riboflavin	0,018
11.	Sorbitol (powder)	94,956
	SUM:	100

(continued)

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[0021] Description of technological process: in the apparatus for wet granulation e.g. in a mixer granulator the ingredients 1 and 2 were placed. A solution of binding agent being a water solution of the ingredient 3 was prepared. The ingredients 1 and 2 were mixed until smooth, however not shorter than 5 minutes. Granulation was performed with use of the water solution of the ingredient 3. The water solution of the ingredient 3 shall have the concentration from 50 to 200 % wt/wt, and it is possible to use maximal ratio of the solvent : ingredient 3 as 1:2. After granulation the granules obtained were calibrated and dried to achieve dryness from 0.5 to 15%. In case of need the dried granules were calibrated.

The ingredient 4 was added. The whole was mixed until smooth, but not less than 3 min. The ingredients 7 to 11 were added and mixed until smooth, but but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient 5 was added. The whole was mixed until smooth, but not less than 3 min. The mass obtained was filled into sachets. The product obtained may be administered directly to a patient or/and used for preparation of a suspension directly before administration.

Example 3

[0022] Quantitative-qualitative composition of the formulation is depicted below.

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No.	Name of the ingredient	% wt/wt
1.	Furazidin	2,77
2.	Lactose monohydrate	1,94
3.	Polyvinylpyrrolidone	1,11
4.	Talc	0,03
5.	Magnesium stearate	0,33
6.	Orange flavor	3,12
7.	Sucrose	55,38
8.	Sorbitol (powder)	35,33
	SUM:	100

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[0023] Description of technological process: in the apparatus for wet granulation e.g. in a mixer granulator the ingredients 1 and 2 were placed. A solution of binding agent being a water solution of the ingredient 3 was prepared. The ingredients 1 and 2 were mixed until smooth, however not shorter than 5 minutes. Granulation was performed with use of the water solution of the ingredient 3. The water solution of the ingredient 3 shall have the concentration from 5 to 50 % wt/wt. After granulation the granules obtained were calibrated and dried to achieve dryness from 0.5 to 15%. In case of need the dried granules were calibrated. The ingredient 4 was added. The whole was mixed until smooth, but not less than 3 min. The ingredients 6 to 8 were added and mixed until smooth, but but not less than 3 min. It is possible to

mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient 4 and 5 was added. The whole was mixed until smooth, but not less than 3 min. The mass obtained was filled into sachets. The product obtained may be administered directly to a patient or/and used for preparation of a suspension directly before administration.

5 Example 4

[0024]

10	No.	Name of the ingredient	% wt/wt
10	1.	Furazidin	2,5
	2.	Lactose monohydrate	1,75
	3.	Polyvinylpyrrolidone	1
15	4.	Talc	0,025
	5.	Magnesium stearate	0,3
	6.	Orange flavor	5,6
20	7.	Sucrose	61,1
20	8.	Mannitol	25
	9.	Citric acid	1
	10.	Sodium citrate	1,35
25	11.	Mixture of polyoxyethylene derivatives of sorbitan and oleic acid	0,375
		SUM:	100

[0025] Description of technological process: A water solution of the ingredients 3 and 11 was prepared. In the apparatus for wet granulation the ingredients 1, 2 and 7 were placed. The whole was mixed until smooth, however not shorter than 3 minutes. It is possible to mix all ingredients together or separately. The mixture was granulated with use of the water solution of the ingredient 3 and 11. In case of need the obtained granules were calibrated. The granules were dried to achieve dryness from 0.5 to 25%. In case of need granules were calibrated. The ingredients 6, 8, 9 and 10 were added to the obtained granules. The whole was mixed until smooth, but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient 4 and 5 was added. The whole was mixed until smooth, but not less than 3 min. The mass obtained was filled into sachets. The product obtained may be administered directly to a patient or/and used for preparation of a suspension directly before administration.

Example 5

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[0026]

N	lo.	Name of the ingredient	% wt/wt
1	1.	Furazidin	13,692
2	2.	Lactose monohydrate	0,479
3	3.	Mixture of copolymers of methacry lie or/and acrylic acid	0,685
4	4.	Talc	0,021
5	5.	Magnesium stearate	0,014
6	6.	Orange flavor	1,534
7	7.	Sucrose	41,076
8	8.	Sorbitol	41,076
9	9.	Citric acid	0,548
1(10.	Sodium citrate	0,739

(continued)

No.	Name of the ingredient	% wt/wt
11.	Mixture of polyoxyethylene derivatives of sorbitan and oleic acid	0,137 '
	SUM:	100

[0027] Description of technological process: A dispersion of the ingredients 3 and 11 was prepared. In the apparatus for wet granulation the ingredients 1, 2 and part of portion of the ingredient 7 were placed. It is possible to use the ingredient 7 in proportion from 0 to 100%. Granulation was performed with use of the solution of the ingredients 3 and 11. Obtained granules were calibrated in case of need, and then dried to achieve dryness from 0.5 to 25%. After drying the granules obtained were calibrated in case of need. The rest of the portion of the ingredient 7 was added to the obtained granules. (if 100% of the portion of the ingredient 7 is used for granulation, this step shall be omitted). Next ingredients 6, 9 and 10 were added to the mixture. The whole was mixed until smooth, but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient in a separate cycle of mixing or/and all ingredient of a suspension directly before administration.

²⁰ Example 6

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[0028]

25	No.	Name of the ingredient	% wt/wt
20	1.	Furazidin	13,692
	2.	Lactose monohydrate	0,479
	3.	Mixture of copolymers of methacrylic or/and acrylic acid	0,685
30	4.	Talc	0,021
	5.	Magnesium stearate	0,014
	6.	Orange flavor	1,534
35	7.	Sucrose	41,076
	8.	Sorbitol	41,076
	9.	Citric acid	0,548
	10.	Sodium citrate	0,739
40	11.	Mixture of polyoxyethylene derivatives of sorbitan and oleic acid	0,137
		SUM:	100

[0029] Description of technological process : A water dispersion of the ingredient 7 was prepared. The water solution of the ingredient 7 shall have the concentration from 50 to 200 % wt/wt, and it is possible to use maximal ratio of the solvent: ingredient 3 as 1:2. Non-used part of the portion of the ingredient 7 will be used in the next step of the process. In the apparatus for wet granulation the ingredients 1 and 2 were placed. It is possible to use the ingredient 8 in proportion from 0 to 100%. Granulation was performed with use of the solution of the ingredient 7. Obtained granules were calibrated in case of need. They were dried to achieve dryness from 0.5 to 25%. A water solution of the ingredient 3 was prepared. Dried granules were fluid coated with the solution of the ingredient 3. To the obtained granules the remaining portions of the ingredients 7 and 8 were added, and then 8 and 9. The whole was mixed until smooth, but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredients 4 and 5 were added. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The product

obtained may be administered directly to a patient or/and used for preparation of a suspension directly before administration.

Example 7

[0030]

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NO.	Name of the ingredient	% wt/wt
1.	Furazidin	64,412
2.	Sucrose	32,206
3.	Mixture of copolymers of methacrylic or/and acrylic acid	3,221
4.	Talc	0,097
5.	Magnesium stearate	0,064
	SUM:	100

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[0031] Description of technological process: A water solution of the ingredient 3 was prepared. In the apparatus for wet granulation the ingredients 1 and 2 were placed. The ingredients 1 and 2 were mixed. Granulation was performed in a fluid bed with use of the solution of the ingredient 3. In case of need the obtained granules were calibrated. The ingredients 4 and 5 were added to the obtained granules. The whole was mixed until smooth, but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient 4 and 5 was added. The whole was mixed until smooth, but not less than 3 min. It is possible to mix each ingredient in a separate cycle of mixing or/and all ingredients together. The ingredient 4 and 5 was added. The whole was mixed until smooth, but not less than 3 min. The product obtained is intended for obtaining pellets or minitablets, that may be coated and constitute a filling for hard capsules or/and may be suspended in a dispersion phase what enables filling of soft capsule or/and hard capsule.

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Claims

- 1. A pharmaceutical oral composition comprising furazidin, **characterized in that** it is in the form of powder or/and granules or/and coated granules, and it comprises from 0.5% by weight to 95% by weight of furazidin and it comprises at least one bulking agent in an amount from 5% by weight to 99% by weight chosen from the group consisting of starch, gelatinized starch, microcrystalline cellulose, lactose, glucose, mannitol, sorbitol, anhydrous colloidal silica, talc, dextrins or/and their mixture.
- 2. The composition according to claim 1, characterized in that it has non-modified release characteristics.
 - 3. The composition according to claim 1, characterized in that it has modified release characteristics.
- 4. The composition according to any of the preceding claims, characterized in that it comprises at least one compound having binding or/and coating properties chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polymers of vinyl alcohol derivatives, chemically modified cellulose derivatives, polyvinylpyrrolidones and/or polyethylene oxides in an amount from 0.1% by weight to 30 % by weight.
- **5.** The composition according to any of the preceding claims, **characterized in that** it comprises at least one compound having emulsifying properties in an amount from 0.1% by weight to 45% by weight chosen from the group consisting of phospholipids, polyoxyethylene sorbitan derivatives, fatty acids and/or fatty alcohols.
 - 6. The composition according to any of the preceding claims, **characterized in that** it comprises at least one compound chosen from the group of surfactants in an amount from 0.1% by weight to 15% by weight.
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- 7. The composition according to any of the preceding claims, **characterized in that** it comprises at least one lubricant in an amount from 0.1% by weight to 10% by weight.
- The composition according to any of the preceding claims, characterized in that it comprises at least one substance chosen from the group consisting of sweetening agents, flavoring agents and buffering agents in an amount from 0.01% by weight to 25% by weight.

- 9. A method of manufacturing the composition as defined in the claims 1-8 comprising furazidin and bulking agent, characterized in that a water or/and organic solution of the substance having binding properties chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polyethylene oxides having concentration of 0.1% by weight to 30 % by weight is prepared, then furazidin in an amount from 0.5% by weight to 95 % by weight is mixed with the substance having emulsifying properties and/or with the bulking agent, then the mixture of furazidin with the substance having emulsifying properties and/or with the bulking agent is granulated with addition of the binding substance solution, after granulation the obtained granules are calibrated and dried, and then they are mixed with bulking agent and/or a lubricant and/or a surfactant and/or a flavoring agent and/or a buffering agent.
 - **10.** The method according to claim 9, **characterized in that** granules directly after drying or after drying and calibration, and before mixing with other substances are coated with coating agents.
- 11. A method of manufacturing the composition as defined in the claims 1-8 comprising furazidin and bulking agent, characterized in that furazidin in an amount from 0.5 to 95% by weight is mixed with a bulking agent chosen from the group consisting of starch, gelatinized starch, microcrystalline cellulose, lactose, glucose, mannitol, sorbitol, talc, anhydrous colloidal silica, dextrins or/and their mixture or/and additionally with a binding agent chosen from the group consisting of saccharides, polyhydric alcohols, polymers of acrylic acid derivatives, polymers of methacrylic acid derivatives, polymers of vinyl alcohol derivatives, chemically modified cellulose derivatives, polyvinylpyrro-lidones and/or polyethylene oxides or/and an emulsifying agent chosen from the group consisting of phospholipids, polyoxyethylene sorbitan derivatives, fatty acids and/or fatty alcohols or/and a surfactant or/and a lubricant or/and a sweetening agent or/and a flavoring agent or/and a buffering agent.

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EUROPEAN SEARCH REPORT

Application Number EP 19 20 9609

	Category	Citation of document with in of relevant passa	dication, where appropriate, ages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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page 1 of 2



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EUROPEAN SEARCH REPORT

Application Number EP 19 20 9609

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page 2 of 2

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

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